



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1P29.R0
True Name	Porcine Reproductive & Respiratory Syndrome-Parvovirus Vaccine, Reproductive Form, Modified Live Virus, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	FLEXParvoPRRS - No distributor specified
Date of Compilation Summary	March 05, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy						
Pertaining to	Porcine Reproductive & Respiratory Syndrome-Parvovirus Vaccine, Reproductive Form, Modified Live Virus, Killed Baculovirus Vector						
Study Purpose	Demonstration of efficacy against porcine parvovirus (PPV) induced reproductive failure						
Product Administration	Administration of one dose of vaccine intramuscularly, and one dose of PPV intramuscularly 21 days later						
Study Animals	Porcine, 5-6 month old healthy gilts: 22 in each of vaccinated and placebo control group (which received PRRS vaccine at day 0 and water at day 21)						
Challenge Description	PPV challenge virus was administered at approximately 40 days of gestation to pregnant gilts						
Interval observed after challenge	Gilts were observed daily for general and reproductive health. Fetuses were delivered from gilts via cesarean at approximately 90 days of gestation. Fetuses were evaluated for fetal condition (normal, necrotic/stillborn, mummy), then tested in the laboratory for PPV by virus isolation from heart, thymus, lung, and/or spleen						
Results	<p>A gilt was considered affected if there was reproductive failure in the litter with at least one necrotic or mummified fetus, or at least one fetus is PPV positive via virus isolation</p> <p>Summary of PPV Affected Gilts:</p> <table border="1"> <thead> <tr> <th>Group</th><th>Number Affected/Total (Percent Affected)</th></tr> </thead> <tbody> <tr> <td>Control</td><td>19/22 (86%)</td></tr> <tr> <td>Vaccinate</td><td>4/22 (18%)</td></tr> </tbody> </table>	Group	Number Affected/Total (Percent Affected)	Control	19/22 (86%)	Vaccinate	4/22 (18%)
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Control	19/22 (86%)						
Vaccinate	4/22 (18%)						
USDA Approval Date	October 07, 2019						

Individual gilt status based on condition of fetuses

Gilt	Total Fetuses	Fetuses Abnormal*	Percent Abnormal	Gilt Status**
Control Group				
103	18	12	66.7%	Affected
108	12	0	0.0%	Negative
109	9	9	100%	Affected
111	15	14	93.3%	Affected
114	16	16	100%	Affected
122	14	9	64.3%	Affected
125	12	12	100%	Affected
126	16	12	75.0%	Affected
129	16	16	100%	Affected
130	6	5	83.3%	Affected
131	8	0	0.0%	Negative
133	15	15	100%	Affected
139	13	13	100%	Affected
143	13	2	15.4%	Affected
152	14	14	100%	Affected
154	11	11	100%	Affected
159	10	0	0.0%	Negative
168	19	19	100%	Affected
187	16	16	100%	Affected
190	15	15	100%	Affected
192	13	11	84.6%	Affected
195	16	16	100%	Affected
Vaccinate Group				
102	15	0	0.0%	Negative
104	17	1	5.9%	Affected
105	14	0	0.0%	Negative
106	13	0	0.0%	Negative
112	15	2	13.3%	Affected
113	14	0	0.0%	Negative
123	16	0	0.0%	Negative
124	15	0	0.0%	Negative
127	13	0	0.0%	Negative
134	10	1	10.0%	Affected
141	12	0	0.0%	Negative
145	18	0	0.0%	Negative
147	3	0	0.0%	Negative
151	14	0	0.0%	Negative
155	9	0	0.0%	Negative
156	11	0	0.0%	Negative
158	10	1	10.0%	Affected
163	12	0	0.0%	Negative
171	12	0	0.0%	Negative
186	19	0	0.0%	Negative
188	13	0	0.0%	Negative
199	16	0	0.0%	Negative

* All fetuses tested negative by virus isolation except one fetus from litter 168, which was positive.

** A gilt with at least one fetus that was aborted, necrotic or mummified, or a positive virus isolation was considered affected.

Individual Fetus Results: Controls

Fetuses are identified by a unique letter/number combination from their position in the left (l) or right (r) uterine horn relative to the uterine bifurcation.

Condition and laboratory result for each fetus is described as:

Ne = necrotic fetus **M** = mummified fetus **0** = Normal fetus **-** = no fetus at this location

Gilt	Fetus Identification																				
	1l	2l	3l	4l	5l	6l	7l	8l	9l	10l	1r	2r	3r	4r	5r	6r	7r	8r	9r	10r	11r
103	0	M	M	M	M	M	0	-	-	-	M	M	M	0	0	0	0	M	M	M	Ne
108	0	0	0	0	0	0	-	-	-	-	0	0	0	0	0	0	-	-	-	-	-
109	Ne	M	M	-	-	-	-	-	-	-	M	M	M	M	N	M	-	-	-	-	-
111	M	M	M	M	M	M	0	-	-	-	M	M	M	M	M	M	M	M	-	-	-
114	M	M	M	M	M	M	M	M	-	-	M	M	M	M	M	M	M	M	-	-	-
122	0	Ne	Ne	0	M	0	0	-	-	-	0	M	M	M	M	M	M	-	-	-	-
125	M	M	M	M	M	M	-	-	-	-	M	M	M	M	M	M	-	-	-	-	-
126	Ne	M	M	M	M	M	M	M	-	-	0	0	M	M	M	M	0	0	-	-	-
129	M	M	M	M	M	M	M	M	-	-	M	M	M	M	M	M	M	M	-	-	-
130	M	M	M	Ne	-	-	-	-	-	-	M	0	-	-	-	-	-	-	-	-	-
131	0	0	0	0	-	-	-	-	-	-	0	0	0	0	-	-	-	-	-	-	-
133	M	M	M	M	M	M	M	M	-	-	M	M	M	M	M	M	M	-	-	-	-
139	M	M	M	M	M	-	-	-	-	-	M	M	M	M	M	M	M	M	-	-	-
143	0	0	0	Ne	M	0	-	-	-	-	0	0	0	0	0	0	0	-	-	-	-
152	M	M	M	M	M	M	M	-	-	-	M	M	M	M	M	M	M	-	-	-	-
154	M	M	M	M	M	M	M	-	-	-	M	M	Ne	M	-	-	-	-	-	-	-
159	0	0	0	0	-	-	-	-	-	-	0	0	0	0	0	0	-	-	-	-	-
168	M	M	M	M*	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	-	-
187	M	M	M	M	M	M	M	M	-	-	M	M	M	M	M	M	M	M	-	-	-
190	M	M	M	M	M	M	M	-	-	-	M	M	M	M	M	M	M	M	-	-	-
192	M	M	M	M	0	0	Ne	-	-	-	M	M	M	M	M	M	-	-	-	-	-
195	M	M	M	M	M	M	M	-	-	-	M	M	M	M	M	M	M	M	-	-	-

*Fetus was positive for PPV virus isolation

Individual Fetus Results: Vaccinates

Fetuses are identified by a unique letter/number combination from their position in the left (l) or right (r) uterine horn relative to the uterine bifurcation.

Condition and laboratory result for each fetus is described as:

Ne = necrotic fetus M = mummified fetus 0 = Normal fetus - = no fetus at this location

Gilt	Fetus Identification																		
	1l	2l	3l	4l	5l	6l	7l	8l	9l	10l	1r	2r	3r	4r	5r	6r	7r	8r	9r
102	0	0	0	0	0	0	0	0	-	-	0	0	0	0	0	0	0	-	-
104	0	0	0	0	0	0	0	0	-	-	0	0	0	M	0	0	0	0	0
105	0	0	0	0	0	0	0	0	-	-	0	0	0	0	0	0	-	-	-
106	0	0	0	0	0	0	0	-	-	-	0	0	0	0	0	0	-	-	-
112	0	M	M	0	0	0	0	0	-	-	0	0	0	0	0	0	0	-	-
113	0	0	0	0	0	0	0	-	-	-	0	0	0	0	0	0	0	-	-
123	0	0	0	0	0	0	0	0	-	-	0	0	0	0	0	0	0	0	-
124	0	0	0	0	0	0	0	0	-	-	0	0	0	0	0	0	0	-	-
127	0	0	0	0	0	0	-	-	-	-	0	0	0	0	0	0	0	-	-
134	0	0	-	-	-	-	-	-	-	-	0	0	0	0	0	0	0	M	-
141	0	0	0	0	0	0	-	-	-	-	0	0	0	0	0	0	-	-	-
145	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0
147	0	0	-	-	-	-	-	-	-	-	0	-	-	-	-	-	-	-	-
151	0	0	0	0	0	0	0	-	-	-	0	0	0	0	0	0	0	-	-
155	0	0	0	0	0	-	-	-	-	-	0	0	0	0	-	-	-	-	-
156	0	0	0	0	0	0	-	-	-	-	0	0	0	0	0	-	-	-	-
158	0	0	M	0	-	-	-	-	-	-	0	0	0	0	0	0	-	-	-
159	0	0	0	0	-	-	-	-	-	-	0	0	0	0	0	0	-	-	-
163	0	0	0	0	0	-	-	-	-	-	0	0	0	0	0	0	0	-	-
171	0	0	0	0	0	0	0	-	-	-	0	0	0	0	0	-	-	-	-
186	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
188	0	0	0	0	0	0	0	-	-	-	0	0	0	0	0	0	-	-	-
199	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	-	-

Study Type	Efficacy																		
Pertaining to	Porcine Reproductive & Respiratory Syndrome (PRRS) virus																		
Study Purpose	Demonstration of efficacy against reproductive failure caused by Porcine Reproductive & Respiratory Syndrome virus																		
Product Administration	Vaccinates: One dose administered intramuscularly (IM) 4 weeks prior to breeding. A PPV booster was administered 3 weeks later. Controls: One dose administered IM 4 weeks prior to breeding. Porcine Parvovirus (PPV). A PPV booster was administered 3 weeks later.																		
Study Animals	Porcine, approximately 6 month old healthy gilts: 20 vaccinated and 15 placebo control (which received PPV vaccine). Gilts were treated to synchronize estrous.																		
Challenge Description	PRRSV challenge virus was administered at approximately 92 days of gestation (120 days after first vaccination)																		
Interval observed after challenge	Piglets were evaluated 21 days post-farrowing.																		
Results	<p>A piglet is considered affected if classified as non-viable (weak, stillborn, or mummified).</p> <p>Table 1: Summary Table</p> <table><tr><th></th><th>Controls Number (%)</th><th>Vaccinates Number (%)</th></tr><tr><td>Number of gilts</td><td>15</td><td>20</td></tr><tr><td>Total number of pigs born</td><td>219</td><td>243*</td></tr><tr><td>Healthy (viable) pigs born</td><td>37 (16.9%)</td><td>133 (54.7%)</td></tr><tr><td>Non-viable (weak, stillborn, mummified) pigs born</td><td>182(83.1%)</td><td>110 (45.3%)</td></tr><tr><td>Pigs survived to weaning</td><td>3 (1.3%)</td><td>102 (42.0%)</td></tr></table> <p>*Two crushed piglets not included in either healthy or non-viable pigs.</p>		Controls Number (%)	Vaccinates Number (%)	Number of gilts	15	20	Total number of pigs born	219	243*	Healthy (viable) pigs born	37 (16.9%)	133 (54.7%)	Non-viable (weak, stillborn, mummified) pigs born	182(83.1%)	110 (45.3%)	Pigs survived to weaning	3 (1.3%)	102 (42.0%)
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USDA Approval Date	May 12, 2020																		

Individual Gilt (Dam) Reproductive Performance and Weaning

Control Group						
Dam ID	Litter Size	Healthy Live Pigs	Weak-born	Stillborn	Mummified	Pigs Weaned (DPF21)
302	12	0	0	12	0	0
312	16	4	1	9	2	1
321	14	0	0	14	0	0
326	12	7	0	5	0	0
327	13	0	0	13	0	0
329	18	3	1	14	0	0
350	17	3	1	13	0	0
351	16	2	0	14	0	0
353	14	3	1	8	2	0
356	15	1	1	13	0	0
357	13	7	1	5	0	1
358	11	2	0	9	0	0
361	17	2	0	15	0	1
367	15	3	0	12	0	0
374	16	0	1	14	1	0
Totals:	219	37	7	170	5	3

Vaccinated Group						
Dam ID	Litter Size	Healthy Live Pigs	Weak-born	Stillborn	Mummified	Pigs Weaned (DPF21)
301	3	2	0	1	0	2
303	9	9	0	0	0	8
308	18*	14	0	3	0	10
309	6	6	0	0	0	5
310	15	6	0	8	1	4
311	13	6	0	7	0	3
314	16	0	4	12	0	0
322	7	6	0	1	0	6
323	10	0	0	10	0	0
334	11	6	0	5	0	3
339	9	9	0	0	0	8
340	11	6	0	5	0	5
341	17	0	0	15	2	0
344	12	7	0	5	0	6
349	15	14	0	1	0	7
352	16	11	0	5	0	8
354	14*	11	0	2	0	10
365	14	0	0	14	0	0
368	14	6	0	8	0	4
370	15	14	1	0	0	13
Totals:	245	133	5	102	3	102

*One pig from this litter was crushed by the sow and is not included in subsequent columns in the table.

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstration of efficacy against the reproductive form of PRRS disease
Product Administration	Administration of one dose intramuscularly
Study Animals	12 pre-breeding sows, divided into 8 vaccinates and 4 controls
Challenge Description	Challenged with PRRS 118 days after vaccination (90 days of gestation)
Interval observed after challenge	Through parturition for sow and piglet condition
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	October 6, 1995

Study Type	Safety																																																															
Pertaining to	All fractions																																																															
Study Purpose	Field Safety in pregnant sows and gilts																																																															
Product Administration	Administration of one dose of Code 1P29.R0 intramuscularly, and one dose of Code 18P5.R0 intramuscularly 21 days later																																																															
Study Animals	420 sows and gilts (pre-breeding, early, and mid-late gestation) at two study sites. Minimum age of 6 months.																																																															
Challenge Description	NA																																																															
Interval observed after vaccination	No challenge. Animals were observed 1-4 hours after each vaccination, and once daily for the duration of the study.																																																															
Results	<table><tr><td>Daily Observations</td><td>Site 1 N=200</td><td>Site 2 N=220</td><td>All N=420</td></tr><tr><td>Healthy (no signs) -All enrolled sows/gilts</td><td>194</td><td>202</td><td>396</td></tr><tr><td>Healthy (no signs) -Dams remaining to farrowing</td><td>178</td><td>190</td><td>368</td></tr><tr><td>Anorexia</td><td>0</td><td>6</td><td>6</td></tr><tr><td>Lameness</td><td>0</td><td>5</td><td>5</td></tr><tr><td>Cough</td><td>0</td><td>3</td><td>3</td></tr><tr><td>Death</td><td>1</td><td>2</td><td>3</td></tr><tr><td>Head tilt – ear disorder</td><td>1</td><td>0</td><td>1</td></tr><tr><td>Injection site granuloma</td><td>1</td><td>0</td><td>1</td></tr><tr><td>Skin abscess</td><td>1</td><td>0</td><td>1</td></tr><tr><td>Skin scab</td><td>0</td><td>1</td><td>1</td></tr><tr><td>Ear infection NOS</td><td>1</td><td>0</td><td>1</td></tr><tr><td>Wound</td><td>0</td><td>1</td><td>1</td></tr><tr><td>Abortion †</td><td>0</td><td>3</td><td>3</td></tr><tr><td>Vaginal tear †</td><td>2</td><td>0</td><td>2</td></tr></table>				Daily Observations	Site 1 N=200	Site 2 N=220	All N=420	Healthy (no signs) -All enrolled sows/gilts	194	202	396	Healthy (no signs) -Dams remaining to farrowing	178	190	368	Anorexia	0	6	6	Lameness	0	5	5	Cough	0	3	3	Death	1	2	3	Head tilt – ear disorder	1	0	1	Injection site granuloma	1	0	1	Skin abscess	1	0	1	Skin scab	0	1	1	Ear infection NOS	1	0	1	Wound	0	1	1	Abortion †	0	3	3	Vaginal tear †	2	0	2
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	<table><tr><td>Number of Piglets</td><td>Category</td><td>Number of Piglets Affected (Percentage)</td></tr><tr><td rowspan="3">5,656</td><td>Healthy</td><td>5,118 (90.5%)</td></tr><tr><td>Mummies or Stillborn</td><td>401 (7.1%)</td></tr><tr><td>Weak born</td><td>137 (2.4%)</td></tr></table>				Number of Piglets	Category	Number of Piglets Affected (Percentage)	5,656	Healthy	5,118 (90.5%)	Mummies or Stillborn	401 (7.1%)	Weak born	137 (2.4%)																																																		
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